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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/796,856	03/09/2004	Ian W. Hunter	65689DIV3(43382)	2436

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EXAMINER	
SODERQUIST, ARLEN	

ART UNIT	PAPER NUMBER
1797	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/796,856	HUNTER, IAN W.	
	Examiner	Art Unit	
	Arlen Soderquist	1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 September 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10 and 12-14* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6,8-10 and 12* is/are rejected.

7)☒ Claim(s) *7,13 and 14* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on September 3, 2008 has been entered.

2. The disclosure is objected to because of the following informalities: the status of the non-provisional parent applications on page 1 of the specification should be updated.

Appropriate correction is required.

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. Claims 1-6, 8-10 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over de Macario (US 4,682,890) in view of Davis US 5,290,705) and optionally in view of Bocker (US 5,786,226). In the patent de Macario describes a carrier and a microsample holder (30) for use in horizontal beam spectrophotometers in place of conventional cuvette supports that normally are used with such spectrophotometers. The microsample holder is formed as a plate having a number of retaining elements preferably in the form of a circular perforated areas for retaining drops of samples to be analyzed by the spectrophotometer. Columns 2-3 teach a sample holder of similar design is known for vertical beam spectrometers. Columns 7-8 teach that the holder (30) is formed with a set of retaining elements, such as a row of four retaining elements (32,34,36,38). The retaining elements are of circular shape having diameters on the order of

about 3 mm, each retaining element being capable of retaining a 5-10 μl sample of liquid to be analyzed. The surfaces of holder (30) other than the circular areas may be coated with a thin layer of hydrophobic material to assure retention of the liquid samples within the circular areas (column 7, lines 12-16). The circular hole diameter permits the surface tension of the liquid sample to retain that sample stably within the confines of the hole. The remainder of holder (30) need not be light transmissive, it is, nevertheless, advantageous to its construction to construct the plate of transparent material, such as glass, plastic, quartz or the like (these materials have inherent hydrophilic properties to be able to hold aqueous samples by surface tension). The holder (30) may be modified within the scope of the invention to have two or more rows of retaining elements, if desired, such as the rectangular pattern shown in FIG. 5 and described in column 7, lines 45-61 or column 11, lines 6-28. It is recognized that the holder is readily usable with the normal support-receptacle and automatic or manual indexing mechanism of conventional horizontal beam spectrophotometers to pass through the center of each sample retained by retaining elements. In this respect the paragraph bridging columns 7-8 teaches that since the overall height, length and width of the carrier are identical (or substantially identical) to the height, length and width of the conventional cuvette support, the carrier is readily usable with the normal support-receptacle and automatic or manual indexing mechanism of conventional horizontal beam spectrophotometers. Thus, the retaining elements are aligned with the analyzing beam that normally passes through windows of the conventional cuvette support. It is seen that the analyzing beam thus passes through the center of each sample retained by retaining elements. The beam passes through only one sample at a time, and as the carrier is indexed, and successive samples are exposed to the beam. The patent also teaches that the de Macario device is meant to reduce the amount of sample required for the testing. The paragraph bridging columns 10-11 teaches the addition of reagents and samples to the holes of the device. This includes anchoring reagents or biologicals to the circular surfaces of the thin, flat dishes or to the inner surfaces of the circular perforated webs which comprise the retaining elements (retaining the regents on the hydrophilic regions as a coating). The hole diameter, plate thickness and density of holes taught by de Macario are greater than claimed, however the patent also teaches that the de Macario device is meant to reduce the amount of sample required for the testing. de Macario also does not teach an array detector.

In the patent Davis teaches a sample support for optical observation which is similar to that taught by de Macario. The drawings show a specimen tray or holder (1) to be employed for optical observation or analysis, and in particular for use in infrared microspectroscopy. The holder (1) includes one or more openings (2) and each opening is provided with an internal ledge or shoulder (3) and a specimen support (4) is supported on each ledge. Each support is preferably a disc-like member having a pair of generally fiat, parallel, opposed surfaces and one or more unobstructed holes (5) extend through the support between the opposed surfaces. Each support is formed of a generally rigid material which will not be attacked by water or acids. Metals, such as stainless steel or gold; or plastic materials such as nylon, polytetrafluoroethylene (Teflon), or Kevlar, can be used to produce the support 4. As shown in the drawings, holes (5) are generally circular in cross section, but it is contemplated that the holes can have other cross-sectional configurations. Davis teaches that holes (5) have a diameter greater than 10 microns, generally in the range of about 10 μm and 13 mm. The cross sectional area or diameter of the holes is correlated with the surface tension of a liquid specimen to be analyzed, such that a film (6) of the liquid will span or enclose the holes, as shown in figure 2. This is taught as being adjustable to provide a quality spectrum based on the thickness of the sample being investigated. Holes (5) can all be of the same diameter or cross-sectional area, or alternately as illustrated in figure 2, the holes can have different diameters. With different diameter holes, the thickness of the liquid film which bridges or encloses the holes will vary with the hole diameter, and thus the operator can select a film thickness to provide the best quality spectrum. By directing an infrared beam through the unsupported film in one of the selected holes, an infrared spectrum of the specimen can be generated. In figure 2 the distance between the two holes is shown as less than the diameter of the holes.

In the patent Bocker teaches quantitative transmission spectroscopy where a sample liquid is applied onto a sample carrier having a net in such a manner that the liquid spreads across the meshes of the net. The liquid on the net is exposed to radiation essentially perpendicularly to the net, and the transmitted radiation is detected. The net accomplishes a dosing of the liquid in such a manner that identical meshes include identical quantities of liquid. For a given net, it is possible to derive the amount of liquid, which is located in a mesh and accessible to radiation, from a net constant. Knowing the amount of liquid detected by the

radiation, it is possible to use the radiation absorption to calculate the concentration of one or several analytes contained in the sample liquid. In column 5 lines 23-36, Bocker teaches the detection of samples in the filled meshes. The net of a sample carrier can be scanned with a light beam which is smaller than the cross section of the meshes similar to the detection method of de Macario. Detecting the transmitted light beam allows differentiating between liquid-filled and non-filled meshes. Advantageously, image recognition can be accomplished with a method where a light beam of a sufficient size is directed onto the net, and the transmitted radiation is detected with a CCD array. Based on the signals generated by the CCD array and using known algorithms for pattern detection, it is possible to distinguish between filled and unfilled meshes and to determine the number of filled meshes.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use smaller diameters within the range taught by Davis because of the ability to further reduce the sample volume and provide a quality spectrum using a single hole. Applicants are directed to the fact that the Courts have held the size of an article to be not a matter of invention; the discovery of an optimum value of a known result effective variable without producing any new or unexpected results is within the skill of the routineer in the art; and mere duplication of parts without any new and unexpected results is within the skill in the routineer in the art. See In re Rose, 105 USPQ 237 (CCPA 1955), In re Boesch, 205 USPQ 215 (CCPA 1980) and In re Harza, 124 USPQ 378 (CCPA 1960), respectively. Thus it would have been obvious to one of ordinary skill in the art at the time of the invention was made to optimize a density of holes and hole dimensions in order to produce a film thickness that would provide a proper spectra as taught by Davis and to provide a sufficient amount of sample to detect. It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the detector array of B6cker in the de Macario method because of the ability to use the detected signal to determine multiple sample containing positions without scanning which Bocker teaches as an advantage.

5. Claims 1-6, 8-10 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over de Macario (US 4,682,890 as explained above) in view of Davis (US 5,290,705 as explained above) and Modlin (US 6,071,748) or Stylli (US 5,985,214).

In the patent Modlin teaches a high-throughput light detection instrument and method. Confocal optics structure enables exclusive light detection from a sensed volume in a composition. Columns 1-3 discuss the use of libraries in the drug discovery process and the benefit of large libraries. In particular column 3, lines 12-35 discuss the need to conserve reagents to reduce the screening costs and the use of microplate formats having well densities as high as 9600 wells (96-9600) on a standard sized microplate. Figure 2 shows the difference in spacings. In the paragraph bridging columns 5-6 Modlin teaches the invention provides an analyzer that enables a wide range of assay formats which can be carefully selected and fine-tuned for screening desired targets with acceptable quality and reliability, while also allowing assays to be run in smaller containers with reduced volumes. These objectives are met, in part, by employing an optical system that minimizes sample interfacial boundary interference, thereby permitting reduction in assay volume in existing formats such as 96 or 384 well plates, and utilization of denser formats such as 768, 1536, 3456, or 9600 well plates. The analyzer also enables assay flexibility by providing the capability of automatically switching between different modes, including photoluminescence, photoluminescence polarization, time-resolved photoluminescence, photoluminescence lifetime, and chemiluminescence modalities. Column 10 lines 25-39 teach detectors including photomultiplier tubes, photodiodes and charge-coupled devices (CCD).

In the patent Stylli teaches systems and methods that utilize automated and integratable workstations for identifying chemicals having useful activity. The invention is also directed to chemical entities and information (e.g., chemical or biological activities of chemicals) generated or discovered by operation of workstations. The automated workstations are programmably controlled to minimize processing times at each workstation and can be integrated to minimize the processing time of the liquid samples from the start to finish of the process. Column 9, lines 8-35 teach it will be advantageous to reduce the volume of the chemical or sample processed because liquid sample processing times benefit from volume reduction as liquid dispensing times are reduced, liquid aspiration times are reduced, diffusion times after addition of a reagent or sample are decreased, temperature control of a smaller volume is more uniform and consumable costs are greatly reduced. To reduce reagent (or chemical) volumes and permit dilution into smaller samples, the sample distribution module can include a liquid handler that comprises a

plurality of nanoliter dispensers that can individually dispense a predetermined volume of less than approximately 2,000 nanoliters of liquid from a predetermined selection of addressable chemical wells into a predetermined selection of addressable sample wells. Preferably, nanoliter dispensers can dispense less than approximately 500 nanoliters, more preferably less than approximately 100 nanoliters, and most preferably less than approximately 25 nanoliters. Dispensing below 25 nanoliters can be accomplished by dispensers described by Stylli. Preferred, minimal volumes dispensed are 5 nanoliters, 500 picoliters, 100 picoliters, 10 picoliters. Preferably, a liquid handler comprises a plurality of nanoliter dispensers that can individually dispense a predetermined volume of liquid from a predetermined selection of addressable chemical wells into a predetermined selection of addressable sample wells. The nanoliter dispensers will typically have a center-to-center distance between each nanoliter dispenser of less than 9.0 mm. This feature permits liquid handling in conjunction with a variety of plate formats. Different types of nanoliter and picoliter dispensers can be used as described and known in the art, as well as such dispensers developed in the future. In one embodiment, the liquid handler can comprise a plurality of nanoliter dispensers that can individually dispense a predetermined volume. Typically, dispensers are arranged in two-dimension array to handle plates of different well densities (e.g., 96, 384, 864 and 3,456). Column 15 line 14 to column 16 line 10 teach a plate stacker used as a plate buffer. Typically, a plate stacker will up/down stack plates of a standard footprint and with different densities which are taught as including 96, 384, 864, and 3,456 well number formats (spacings of- l cm to l mm) or greater (e.g., 6,912 or 13,024, spacings of less than l mm)). The operation of the sample distribution module will usually be highly flexible to satisfy the needs of different liquid processing applications. Predefined operations can be made available for selection by an end user, or end users may create an entirely new method. Operations can be performed on a wide variety of plates and batch sizes of plates can vary. Sample plates and chemical plates may be selected with a different format from distribution plates (e.g., daughter plates). The sample distribution module will typically provide for a stand alone mode and can be preferably integrated with a data processing and integration module.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use smaller diameters within the range taught by Davis because of the ability to

further reduce the sample volume and provide a quality spectrum using a single hole and thereby provide the cost and time advantages taught by Modlin and Stylli. Applicants are directed to the fact that the Courts have held the size of an article to be not a matter of invention; the discovery of an optimum value of a known result effective variable without producing any new or unexpected results is within the skill of the routineer in the art; and mere duplication of parts without any new and unexpected results is within the skill in the routineer in the art. See In re Rose, 105 USPQ 237 (CCPA 1955), In re Boesch, 205 USPQ 215 (CCPA 1980) and In re Harza, 124 USPQ 378 (CCPA 1960), respectively. Thus it would have been obvious to one of ordinary skill in the art at the time of the invention was made to optimize a density of holes and hole dimensions in order to produce a film thickness that would provide a proper spectra as taught by Davis and to provide a sufficient amount of sample to detect. It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the detector arrays of Modlin and Stylli in the de Macario method because of the ability to use the detected signal to determine multiple sample containing positions without scanning since the Modlin and Stylli references clearly show that the art of analysis devices had developed to the point that signal can be detected from wells spaced at the level required by the claims.

6. Claims 7 and 13-14 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

7. Applicant's arguments filed September 3, 2008 have been fully considered but they are not persuasive. Relative to the set of distinct substances in de Macario being "anchored" in a manner that is different from the invention as claimed in claims 1 and 10, examiner notes that there is nothing in the broad claims that would prevent the distinct substances from being "retained" to the hydrophilic areas by anchoring them at that position. If the claims only cover retaining them so that they can be resuspended or dissolved, Claims 7 and 13-14 are not further limiting. However, the scope of "retain" is broad enough to cover the anchoring of reagents as shown by the use of retaining elements for the structure that the reagents are anchored on. Thus that argument is not commensurate in scope with the rejected claims. Since that is the only argument that applicant has made, with respect to all of the claims, it is persuasive only for those claims that are of that scope: 7 and 13-14

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Arlen Soderquist whose telephone number is (571)272-1265. The examiner can normally be reached on Monday-Thursday and Alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Arlen Soderquist/
Primary Examiner, Art Unit 1797